## SETTLEMENT AGREEMENT

#### I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively the "United States"); and Mercy Haverford Hospital d/b/a Mercy Community Hospital ("Mercy Community") and the qui tam Relator, Maryann Gola ("Relator"), (hereafter referred to as "the Parties"), through their authorized representatives.

## II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. Mercy Community is a non-profit, non-stock corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 2000 Old West Chester Pike, Havertown, Pennsylvania. At all times relevant to this agreement Mercy Community operated as an acute care hospital.
- B. The United States contends that Mercy Community submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg.
  - C. On July 14, 2000, the Relator filed a qui tam

Complaint under seal, alleging violations of the False Claims Act, 31 U.S.C. §§ 3729-3733\_ by Mercy Community in a case Docketed at Civ. No. 00-3564 (E.D. Pa.) (the "Civil Action"). Thereafter, the United States investigated the allegations raised in the qui tam action and is prepared to intervene, contending that it has certain civil monetary claims against Mercy Community under the False Claims Act, other federal statutes and/or common law doctrines, for engaging in the following conduct during the period from May 1, 1990 to August 5, 1997: participating in relationships with Dr. Leonard Ginsburg ("Ginsburg"), Retina and Diabetic Eye Services ("RDES"), and Retina and Diabetic Eye Institute ("RDEI"), wherein Mercy Community provided space, equipment, personnel, supplies and other services to Ginsburg, RDES and RDEI in violation of the anti-kickback statute, 42 U.S.C. § 1320a-7b(b) and the "Stark" law, 42 U.S.C. § 1395nn, and submitting claims for reimbursement to Federal healthcare programs in connection with the services provided by Ginsburg (hereinafter referred to as the "Covered Conduct").

D. Mercy Community does not admit the contentions of the United States as set forth in Paragraph C, above and to the contrary, contends that its conduct was at all times lawful and appropriate. Mercy Community denies that it provided space, equipment, personnel, supplies or other services to Ginsburg in violation of the "Stark" law or the anti-kickback statute, and further denies that it submitted any unlawful claims for

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reimbursement in connection with the Ginsburg relationship and/or acted in violation of the False Claims Act or any other statutory or common law doctrine.

E. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement as set forth below.

## III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

- 1. Mercy Community agrees to pay to the United States \$1,036,925.00 (the "Settlement Amount"), as follows: Mercy Community agrees to make payment of the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney. Mercy Community agrees to make one-half of this electronic funds transfer (\$518,462.50) no later than ten days after receipt of a fully executed version of this Settlement Agreement signed by each signatory to the Agreement, and the remaining one-half (\$518,462.50) no later than January 2, 2003.
  - Subject to the exceptions in Paragraph 4 below,

in consideration of the obligations of Mercy Community set forth in this Agreement, conditioned upon Mercy Community's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) agrees to release Mercy Community together with its current and former parent corporations, current owners, current officers, current directors, current employees, and the successors and assigns of any of them from any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; "Stark" law, 42 U.S.C. § 1395nn; the Civil Monetary Penalties Law, 42 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Covered Conduct.

3. In consideration of the obligations of Mercy Community set forth in this Agreement, conditioned upon Mercy Community's payment in full of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Mercy Community under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the Covered Conduct, except as reserved in Paragraph 4, below, and as

reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Mercy Community from the Medicare, Medicaid or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 4, below.

- 4. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Mercy Community) are any and all of the following:
- (1) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
  - (2) Any criminal liability;
- (3) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (4) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (5) Any claims based upon such obligations as are created by this Agreement, including those created by the Corporate Integrity Agreement referred to in Paragraph 5 below;
  - (6) Any claims based on a failure to deliver

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items or services due;

- (7) Any civil or administrative claims against former directors, officers, employees, agents or shareholders of defendant Mercy Community who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct.
- 5. Mercy Community has entered into a Corporate Integrity Agreement with HHS-OIG, which is incorporated into this Agreement and attached as Exhibit A. Immediately upon execution of this Agreement the CIA will take effect. Mercy Community represents that it is presently not operating an acute care facility and not participating in as a provider or supplier with the Federal health care programs. Accordingly, the obligations assumed by Mercy Community under the CIA shall be suspended until such time as Mercy Community resumes participation as a provider or supplier with the Federal health care programs. In the event Mercy Community commences participation in Federal health care programs as a provider of acute care services at any time during the term of the CIA, Mercy Community shall immediately notify the OIG and the CIA shall be re-activated for the remainder of the term of the CIA. In the event Mercy Community commences participation as a provider or supplier with the Federal health

care programs in any other capacity, Mercy will notify OIG as soon as it commences such participation and, upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified. For purposes of this CIA, the term "participation as a provider or supplier with the Federal health care programs" does not encompass Mercy Community's possession of an ownership interest in the Mercy Surgery Center located at 2010 Westchester Pike, Havertown, PA.

- defenses Mercy Community waives and will not assert any defenses Mercy Community may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Settlement bars a remedy sought in such criminal prosecution or administrative action.

  Mercy Community agrees that this settlement is not punitive in purpose or effect. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.
- 7. Mercy Community fully and finally releases the United States, its agencies, employees, servants, and agents from

any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Mercy Community has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

- 8. The United States will, pursuant to 31 U.S.C. §
  3730(d)(1), pay the Relator her share of each payment of the
  Settlement Amount made to it, within a reasonable time of its
  receipt of same from Mercy Community. The United States has no
  obligation to disburse any monies to the Relator unless and until
  the United States receives the Settlement Amount from Mercy
  Community. Mercy Community's payment to the Relator of the
  Relator's attorneys' fees and costs, as required by 31 U.S.C. §
  3730(d), will be resolved by separate agreement between the
  Relator and Mercy Community, or by Court Order.
- 9. The Relator and Mercy Community agree that the Relator's Share and the Relator's attorneys' fee, referenced in Paragraph 8, above, when the latter is resolved by separate agreement or by Court Order, shall be in full satisfaction of all claims, known or unknown, that the Relator and her attorneys may have against Mercy Community and its partners, affiliates, divisions, parents, subsidiaries, predecessors, successors, assigns, transferees, attorneys and each of their current or

former directors, officers, and employees, on account of her initiation of the Civil Action, or any other theory, and is inclusive of all claims the Relator, her successors, assigns, or counsel may have for attorneys' fees, costs and expenses in connection with the Civil Action or any other theory. For and in consideration of such payment, the Relator, for herself, her heirs, successors, assigns, attorneys and agents releases and forever discharges Mercy Community, and each of its partners, parents, affiliates, divisions, subsidiaries, predecessors, successors, assigns, transferees, attorneys and each of their current or former directors, officers, and employees, from any and all actions, claims, causes of action, suits, charges, demands, debts, liabilities, past, present or future obligations,

successors, assigns, transferees, attorneys and each of their current or former directors, officers, and employees, from any and all actions, claims, causes of action, suits, charges, demands, debts, liabilities, past, present or future obligations, damages, judgments, executions, accounts, sums of money, reckonings, controversies, losses, actions and causes of action of every kind and nature whatsoever, in law or in equity, whether or not known or suspected at this time, which the Relator or her attorneys ever had, owned or held or hereafter can, shall or may have against Mercy Community either in an individual, qui tam, or representative capacity.

Mercy Community and each of its partners, parents, affiliates, divisions, subsidiaries, predecessors, successors, assigns, transferees, attorneys and each of its current or former directors, officers and employees, release and forever discharge

Relator, and each of her heirs, successors, assigns, attorneys and agents, from any and all actions, claims, causes of action, suits, charges, demands, debts, liabilities, past, present or future obligations, damages, judgments, executions, accounts, sums of money, reckonings, controversies, losses, actions and causes of action of every kind and nature whatsoever, whether or not known or suspected at this time, which Mercy Community, and each of its parents, partners, affiliates, divisions,

subsidiaries, predecessors, successors, assigns, transferees, attorneys and each of their current or former directors, officers and employees, ever had, owned or held or hereafter can, shall or may have against the Relator.

- 10. Relator agrees to release the United States, its officers, agents and employees, from any liability arising from the filing of the Civil Action, including any claims to a share of the proceeds pursuant to 31 U.S.C. § 3730(d), subject to her receipt of the Relator Share, as described in Paragraph 8.
- 11. The Amount that Mercy Community must pay pursuant to this Agreement by electronic wire transfer pursuant to Paragraph 1 above, will not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any State payer, related to the Covered Conduct; and Mercy Community agrees not to resubmit to any Medicare carrier or intermediary or any State

payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

- 12. Mercy Community agrees to the following:
- (a) <u>Unallowable Costs Defined</u>: that all costs (as defined in the Federal Acquisition Regulations (FAR), 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf on Mercy Community, its present or former officers, directors, employees, shareholders, and agents in connection with:
  - (1) the matters covered by this Agreement,
- (2) the United States' audit(s) and civil
  investigations(s) of the Covered Conduct,
- (3) Mercy Community's investigation, defense, and any corrective actions undertaken in direct response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),
- $\mbox{(4)} \quad \mbox{the negotiation and performance of this} \\ \mbox{Agreement, and} \quad$
- (5) the payment Mercy Community makes to the United States pursuant to this Agreement and any payments that Mercy Community may make to relators, and

- (6) the negotiation of the CIA, and the obligations undertaken pursuant to the CIA to prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this sub-paragraph that may apply to compliance costs affects the status of costs that are not allowable based on any other authority applicable to Mercy Community.
- (All costs described or set forth in this Paragraph 12(a) are hereafter, "unallowable costs").
- (b) Future Treatment of Unallowable Costs: These unallowable costs will be separately estimated and accounted for by Mercy Community, and Mercy Community will not charge such unallowable costs difectly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Mercy Community or any of its subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- (c) Treatment of Unallowable Costs Previously

  Submitted for Payment: Mercy Community further agrees that within

  90 days of the effective date of this Agreement, it will identify
  to applicable Medicare and TRICARE fiscal intermediaries,

carriers, and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Mercy Community or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Mercy Community agrees that the United States, at a minimum, will be entitled to recoup from Mercy Community any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or request for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Mercy Community or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Mercy Community or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the

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United States to examine or reexamine the unallowable costs described in this Paragraph.

13. Mercy Community covenants to cooperate fully and truthfully with the United States' investigation of individuals and entities not specifically released in this Agreement. Upon reasonable notice, Mercy Community will make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. In addition, Mercy Community agrees, pursuant to a limited waiver of the attorney-client privilege, to permit the United States to interview Alice Gosfield, Esquire ("Gosfield"), attorney for Mercy Community, regarding her knowledge and participation in negotiations between Mercy Community and Ginsburg relating to the relationship between Mercy Community and Ginsburg and the termination thereof (the "Ginsburg matter"), and to inspect and copy Gosfield's file relating to the Ginsburg matter, and it further agrees that it will not assert the attorney-client privilege in the event that Gosfield is subpoenaed to testify in any forum by the United States regarding the Covered Conduct and the Ginsburg matter. It is expressly understood and agreed between the parties that the limited waiver of the attorneyclient privilege for the purposes of providing the interview, testimony and document production described in this paragraph

does not constitute a general subject-matter waiver of the attorney-client privilege, and neither the United States, nor the Relator, nor anyone acting on its or her behalf, will attempt to assert on the basis of the limited waiver, the interview, testimony or document production facilitated thereby, or any other aspect of the Settlement Agreement that Mercy Community or any affiliated entity has waived its attorney-client privilege with regard to the Ginsburg matter or any other matter.

- 14. This Agreement is intended to be for the benefit of the Parties, only, and by this instrument the Parties do not release any claims against any other person or entity.
- 15. Mercy Community agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Mercy Community waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.
- 16. Mercy Community expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. § 547(b)(3), and will remain solvent following its payment to the United States hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (i) have intended that the mutual promises, covenants and obligations set forth

herein constitute a contemporaneous exchange for new value given to Mercy Community, within the meaning of 11 U.S.C. § 547(c)(1), and (ii) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

- 17. With the exception of the Relator's attorneys fees as described in Paragraph 8, each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 18. Mercy Community and the Relator represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 19. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Eastern District of Pennsylvania, except that where a dispute arises regarding the Corporate Integrity Agreement, such dispute shall be resolved pursuant to the provisions of the Corporate Integrity Agreement.
- 20. The parties agree that they will jointly request that the Court dismiss, with prejudice, all allegations against Mercy Community, in the *qui tam* action captioned at Civ. No. 00-3564

- 21. With the exception of any agreement between the Relator and Mercy Community as to attorneys fees, as described in Paragraph 8, this Agreement and the Corporate Integrity Agreement which is incorporated by reference, constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only Mercy Community and OIG-HHS must agree in writing to modification of the Corporate Integrity Agreement, pursuant to Paragraph XI.C of the Corporate Integrity Agreement.
- 22. The undersigned individuals signing this Agreement on behalf of Mercy Community represent and warrant that they are authorized by Mercy Community to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.
- 23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.
- 24. This Agreement is effective on the date of signature of the last signatory to the Agreement.

## THE UNITED STATES OF AMERICA

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DATED: 10/2/02	BY:	H. Gerfin Moulin 1. PATRICK E. MEEHAN United States Attorney
		Eastern District of Pennsylvania
DATED: 101	BY:	JAMES G. SHEEHAN Chief, Civil Division
		United States Attorney's Office Eastern District of Pennsylvania
DATED: 10/1/02	BY:	SUSAN SHINKMAN Assistant United States Attorney Eastern pistrict of Pennsylvania
DATED: 10-1-07	BY:	DAVID R. HOFFMAN Assistant United States Attorney Eastern District of Pennsylvania
DATED: 9/24/62	BY:	LEWIS MORRIS Assistant Inspector General Office of Counsel
	. •	to the Inspector General Office of Inspector General United States Department of Health and Human Services

## MERCY COMMUNITY HOSPITAL - DEFENDANT

DATED: September 16, 2002

BY:

GAVIAY KERR
President
Mercy Haverford Hospital d/b/a
Mercy Community Hospital

DATED: 9/17/02

BRIAN M. PETERS, ESQUIRE
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## RELATOR

HOWARD BRUCE KLEIN, ESQUIRE
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Philadelphia, PA 19103
Counsel for Relator

BY:

BRUCE J. GOLDSTEIN, ESQUIRE Wade, Goldstein, Landau & Abruzzo, PC 61 Cassatt Avenue Berwyn, PA 19312

# CORPORATE INTEGRITY AGREEMENT BETWEEN THE

OFFICE OF INSPECTOR GENERAL OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND
MERCY HAVERFORD HOSPITAL, D/B/A MERCY COMMUNITY HOSPITAL

### I. PREAMBLE

Mercy Haverford Hospital, d/b/a, Mercy Community Hospital ("Mercy Community") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, physicians, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). Contemporaneously with this CIA, Mercy Community is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

## II. TERM OF THE CIA

The period of the compliance obligations assumed by Mercy Community under this CIA shall be three years from the Effective Date of this CIA (unless otherwise specified). The "Effective Date" of this CIA shall be the date on which the final signatory of this CIA executes this CIA. Mercy Community represents that it is presently not operating an acute care facility and not participating as a provider or supplier with the Federal health care programs. Accordingly, the obligations assumed by Mercy Community under the CIA shall be suspended until such time as Mercy Community resumes participation as a provider or supplier with the Federal health care programs. In the event Mercy Community commences participation in Federal health care programs as a provider of acute care services at any time during the term of the CIA, Mercy Community shall immediately notify the OIG and the CIA shall be re-activated for the remainder of the term of the CIA. In the event Mercy Community commences participation as a provider or supplier with the Federal health care programs in any other capacity, Mercy will notify OIG as soon as it commences such participation and, upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or

modified. For purposes of this CIA, the term "participation as a provider or supplier with the Federal health care programs" does not encompass Mercy Community's possession of an ownership interest in the Mercy Surgery Center located at 2010 Westchester Pike, Havertown, PA.

In the event that this CIA becomes activated at any time during its three-year term, Mercy Community's obligations under the CIA shall commence as of the activation date, and Sections VII, VIII, IX, X, and XI shall then expire no later than 120 days from the OIG's receipt of: (1) Mercy Community's final annual report; or (2) any additional materials submitted by Mercy Community pursuant to the OIG's request, whichever is later. In the event this CIA is not activated during the three-year term, all provisions of the CIA shall expire on the Expiration Date.

## III. CORPORATE INTEGRITY OBLIGATIONS

Mercy Community hereby agrees to maintain or participate in a compliance program that includes the following elements:

## A. Compliance Officer and Committee.

Compliance Officer. Mercy Community has appointed an individual to serve as its Compliance Officer. This individual also serves as the Compliance Officer for the Mercy Health System ("MHS") Corporate Compliance Program, to which Mercy Community is subject. The Compliance Officer is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer is a member of senior management of MHS. The Compliance Officer will make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mercy Community, and is authorized to report on such matters to the Board of Directors at any time. The Compliance Officer is responsible for monitoring the day-to-day compliance activities engaged in by Mercy Community as well as for any reporting obligations created under this

Mercy Community shall report to the OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA within 15 days of such a change.

 Compliance Committee. Within 90 days of the Effective Date of this CIA, Mercy Community shall appoint a Compliance Committee, which may be the existing Compliance Committee for MHS. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management of Mercy Community or MHS necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Mercy Community shall report to the OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA within 15 days of such a change.

#### B. Written Standards.

- 1. Code of Conduct. Mercy Community, either individually or through its participation in the MHS Corporate Compliance Program, shall establish a written Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 90 days of the Effective Date of this CIA. Mercy Community shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, address:
  - a. Mercy Community's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
  - Mercy Community's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Mercy Community's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);
  - the requirement that all of Mercy Community's Covered
    Persons shall be expected to report to the Compliance Officer
    or other appropriate individual designated by Mercy
    Community suspected violations of any Federal health care
    program requirements or of Mercy Community own Policies
    and Procedures;

- d. the possible consequences to both Mercy Community and Covered Persons of failure to comply with Federal health care program requirements and with Mercy Community's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in section III.E, and Mercy Community's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

Within 90 days of the Effective Date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Mercy Community's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within one month after becoming a Covered Person or within 90 days of the Effective Date of the CIA, whichever is later.

Mercy Community shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

- 2. Policies and Procedures. Mercy Community, either individually or through its participation in the MHS Corporate Compliance Program, will establish and maintain written Policies and Procedures regarding the operation of Mercy Community's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
  - the subjects relating to the Code of Conduct identified in section III.B.1;
  - b. business arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries, in violation of 42 U.S.C. § 1320a-7b(b) (the "anti-kickback" statute) and 42 U.S.C. § 1395nn (the "Stark" statute);
  - procedures requiring legal review of all contracts and agreements that are entered into with individuals or entities who are either directly or indirectly in a position to make referrals to Mercy Community;

- d. measures to ensure that the contracts reflect the actual arrangements;
- measures to ensure that individuals in a position to refer patients, items, or services to Mercy Community do not receive remuneration, either directly or indirectly, for referrals;
- f. measures to ensure that fair market value analyses are appropriately and accurately completed; and
- g. measures to ensure that all payments to physicians comply with the Federal health care program requirements.

As part of its policies and procedures, Mercy Community is subject to the MHS physician contracting policy that seeks to ensure that Mercy Community's relationships with physicians conform to current statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs. The MHS physician contracting policy shall remain in effect for the duration of the CIA.

Within 90 days of the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Mercy Community shall assess and update as necessary the Policies and Procedures, including the physician contracting policy. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

### C. Training and Education.

- 1. General Training. Within 90 days of the Effective Date of this CIA, Mercy Community shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain Mercy Community's:
  - a. CIA requirements; and
  - Mercy Community's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the Effective Date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

- 2. Specific Training. Within 90 days of the Effective Date of this CIA, each Covered Person who is involved in preparing or negotiating contracts for health care services or who is involved in preparing or submitting claims for reimbursement to the Medicare, Medicaid and other Federal health care programs on behalf of Mercy Community (hereinafter referred to as "Relevant Covered Persons") shall receive at least two hours of specific training in addition to the general training required above. This specific training shall include a discussion of:
  - the anti-kickback and Stark statutes, and the regulations and other guidance related to these statutes;
  - the personal obligation of each individual to make appropriate and accurate representations regarding coverage and billing for items and services provided by Mercy Community;
  - c. applicable legal requirements;
  - d. applicable reimbursement statutes, regulations, and program requirements and directives;
  - e. the legal sanctions for improper sales or marketing strategies or arrangements; and
  - f. examples of proper and improper marketing strategies and arrangements.

Persons providing the training must be knowledgeable about the subject area. This training may, at Mercy Community's option, be provided through an appropriate webbased compliance education program.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the Effective Date of this CIA, whichever is later. A Mercy Community employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his/her applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least one hour of specific training annually.

3. <u>Certification</u>. Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

#### D. Review Procedures.

- 1. Physician Contract Reviews. As part of MHS' physician contracting policy, to which Mercy Community is subject, prior to execution, all physician contracts are subjected to an appropriate valuation and, in some instances, review and approval by the Human Resources Committee of the MHS Board ("HRC"). The persons conducting each such valuation and each such HRC review shall document their findings and recommendations. Upon request, and subject to the provisions of Section IX below, Mercy Community shall make available to the OIG the physician contracts that have been reviewed as well as all written reports of the valuations and HRC reviews, and such documentation shall be provided to the OIG with Mercy Community's Annual Report.
- 2. Unallowable Cost Review. Mercy Community shall conduct a review of its compliance with the unallowable cost provisions of the Settlement Agreement.
  - Mercy Community shall determine whether Mercy Community has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Mercy Community or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, Mercy Community may need to review cost reports and/or

financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

- b. Unallowable Cost Review Report. Mercy Community shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include: Mercy Community's findings and supporting rationale regarding the Unallowable Costs Review and whether Mercy Community has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
- 3. Validation Review. In the event the OIG has reason to believe that:
  (a) Mercy Community's Physician Contract Review or Unallowable Cost Review fails to conform to the requirements of this CIA, or (b) that the findings or results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Physician Contract Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings are inaccurate ("Validation Review"). Mercy Community agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Mercy Community's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Mercy Community of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Mercy Community may request a meeting with the OIG to discuss the results of any Physician Contract Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Physician Contract Review or Unallowable Cost Review to correct the inaccuracy of the Review; and/or propose alternatives to the proposed Validation Review. Subject to the provisions of Section IX below, Mercy Community agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Review with Mercy Community prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

#### E. Disclosure Program.

Mercy Community has established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Mercy Community's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. Mercy Community shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality will be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Mercy Community shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

#### F. Ineligible Persons.

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- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred, suspended or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, suspended debarred or otherwise declared ineligible.
- 2. Screening Requirements. Mercy Community shall not hire as employees or engage as contractors or grant staff privileges to any Ineligible Person. To

prevent hiring or contracting with any Ineligible Person, Mercy Community shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) Mercy Community to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Review and Removal Requirement. Within 90 days of the Effective Date of this CIA, Mercy Community shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, Mercy Community shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists semi-annually. In addition, Mercy Community shall require employees and contractors to disclose immediately any debarment, suspension, exclusion, or other event that makes the employee an Ineligible Person.

If Mercy Community\_has actual notice that an employee or contractor and physician with staff privileges has become an Ineligible Person, Mercy Community shall remove such person from responsibility for, or involvement with, Mercy Community's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Mercy Community has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, Mercy Community shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

## G. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, Mercy Community shall notify OIG, in writing, of any ongoing investigation known to Mercy Community or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Mercy

Community has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Mercy Community shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

## H. Reporting.

- 1. Overpayments
  - a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Mercy Community has received in excess of the amount due and payable under any Federal health care program requirements.
  - Reporting of Overpayments. If, at any time, Mercy Community identifies or learns of any overpayments, Mercy Community shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of rdentification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, Mercy Community shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, Mercy Community shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

- 2. Material Deficiencies.
  - a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:
    - (i) a substantial overpayment; or
    - (ii) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

- b. Reporting of Material Deficiencies. If Mercy Community determines through any means that there is a Material Deficiency, Mercy Community shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
  - (i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:
    - the payor's name, address, and contact person to whom the overpayment was sent; and
    - (B) the date of the check and identification number (or electronic transaction number) by which the overpayment was repaid/refunded;
  - (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
  - (iii) a description of Mercy Community's actions taken to correct the Material Deficiency; and

(iv) any further steps Mercy Community plans to take to address the Material Deficiency and prevent it from recurring.

### IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this CIA, Mercy Community changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mercy Community shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

#### V. ANNUAL REPORTS

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Mercy Community shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Mercy Community's compliance activities for each of the three one-year periods beginning on the Effective Date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

#### A. Contents of Annual Report

Each Annual Report shall include:

- 1. the name, address, phone number, and position description of the Compliance Officer required by section III.A, and a summary of other non-compliance job responsibilities the Compliance Officer may have;
- 2. the names and positions of the members of the Compliance Committee required by section III.A;
- 3. in the first Annual Report, a copy of Mercy Community's Code of Conduct required by section III.B.1, and in subsequent Annual Reports a summary of any significant changes or amendments to the Code of Conduct;
- 4. in the first Annual Report, a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;

- 5. in the second and third annual reports, a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
- 6. a copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
  - 7. a certification by the Compliance Officer that:
    - a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;
    - b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;
    - c. Mercy Community has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs; and
    - d. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons.

The documentation supporting this certification shall be available to OIG, upon request.

- 8. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 9. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable) and other Federal health care programs.

Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate overpayment report;

- a summary of the disclosures in the disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients (the first Annual Report should also contain a description of the disclosure program);
- 11. a description of any personnel actions (other than hiring) taken by Mercy Community as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section:
- 12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 13. a description of all changes to the most recently provided list (as updated) of Mercy Community's locations (including locations and mailing addresses) as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number;
- 14. copies of all documentation related to valuations and reviews of physician contracts pursuant to section III.D.1; and
  - 15. the certification required by section V.B.
- 16. a complete copy of all reports prepared pursuant to Mercy Community's unallowable cost review conducted pursuant to Section III.D.2.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

B. <u>Certifications</u>. The Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Mercy Community is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has

made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

Designation of Information: Mercy Community shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Mercy Community shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

#### VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

## OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services Cohen Building, Room 5527 330 Independence Avenue, SW Washington, DC 20201 Phone: 202-619-2078

Fax:

202-205-0604

## Mercy Community:

James K. Seaman, Compliance Officer Mercy Health System, Inc. One West Elm Street Conshohocken, PA 19428-2007

Phone: Fax:

610-567-6100 610-567-6820

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

#### VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may, subject to the provisions of Section IX, below, examine or request copies of Mercy Community's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Mercy Community's locations for the purpose of verifying and evaluating: (a) Mercy Community's compliance with the terms of this CIA; and (b) Mercy Community's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Mercy Community to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Mercy Community's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Mercy Community agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Mercy Community's employees may elect to be interviewed with or without a representative of Mercy Community present.

#### VIII. DOCUMENT AND RECORD RETENTION

Mercy Community shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for four years (or longer if otherwise required by law).

#### IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Mercy Community prior to any release by OIG of information submitted by Mercy Community pursuant to its obligations under this CIA and identified upon submission by Mercy Community as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Mercy Community shall have the rights set forth at 45 C.F.R. § 5.65(d). Mercy Community shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as a waiver by Mercy Community of its attorney-client,

work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Mercy Community's obligation to comply with the provisions of this CIA with regard to any documents or information not covered by an applicable privilege.

## X. BREACH AND DEFAULT PROVISIONS

Mercy Community is expected to fully and timely comply with all of its CIA obligations.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Mercy Community and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mercy Community fails to have in place any of the obligations described in section III:
  - a. a Compliance Officer;
  - b. a Compliance Committee;
  - c. a written Code of Conduct;
  - d. written Policies and Procedures;
  - e. a requirement that Covered Persons be trained; and
  - f. a Disclosure Program.

- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mercy Community fails to meet any of the deadlines for the submission of the Annual Reports to OIG.
- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Me0rcy Community employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Mercy Community's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal

funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Mercy Community can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

- 4. A Stipulated Penalty of \$1,500 for each day Mercy Community fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date Mercy Community fails to grant access.)
- 5. A Stipulated Penalty of \$1,000 for each day Mercy Community fails to comply fully and adequately with any obligation of this CIA. In its notice to Mercy Community, OIG shall state the specific grounds for its determination that Mercy Community has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Mercy Community must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Mercy Community receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.
- B. Timely Written Requests for Extensions. Mercy Community may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Mercy Community fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Mercy Community receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

#### Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that Mercy Community has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Mercy Community of: (a) Mercy Community's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Mercy Community shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Mercy Community elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Mercy Community cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.
- 4. Independence from Material Breach Determination. Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Mercy Community has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.
  - D. Exclusion for Material Breach of this CIA
    - 1. Definition of Material Breach. A material breach of this CIA means:
      - a failure by Mercy Community to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in section III.H;
      - a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A; or
      - a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Mercy Community constitutes an independent basis for Mercy Community's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Mercy Community has materially breached this CIA and that exclusion should be imposed, OIG shall notify Mercy Community of: (a) Mercy

Community's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

- 3. Opportunity to Cure. Mercy Community shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
  - Mercy Community is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;
  - b. the alleged material breach has been cured; or
  - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Mercy Community has begun to take action to cure the material breach; (ii) Mercy Community is pursuing such action with due diligence; and (iii) Mercy Community has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, Mercy Community fails to satisfy the requirements of section X.D.3, OIG may exclude Mercy Community from participation in the Federal health care programs. OIG will notify Mercy Community in writing of its determination to exclude Mercy Community (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Mercy Community wishes to apply for reinstatement, Mercy Community must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

## E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to Mercy Community of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Mercy Community shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated

Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Mercy Community was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Mercy Community shall have the burden of proving its full and timely compliance and the stepstaken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to stipulated penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Mercy Community to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Mercy Community requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:
  - a. whether Mercy Community was in material breach of this CIA;
  - b. whether such breach was continuing on the date of the Exclusion Letter; and 0
  - c. whether the alleged material breach could not have been cured within the 30-day period, but that:
    - (i) Mercy Community had begun to take action to cure the material breach within that period;
    - Mercy Community has pursued and is pursuing such action with due diligence; and

(iii) Mercy Community provided to OIG within that period a reasonable timetable for curing the material breach and Mercy Community has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Mercy Community, only after a DAB decision in favor of OIG. Mercy Community's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Mercy Community upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Mercy Community may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Mercy Community agrees to waive [its/his/her] right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Mercy Community, Mercy Community will be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Mercy Community and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Mercy Community;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned Mercy Community signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

## ON BEHALF OF MERCY HAVERFORD HOSPITAL D/B/A MERCY COMMUNITY HOSPITAL

GAVINAERR, PRESIDENT

Syphia 16, 2002 DATE

BRIAN M. PETERS, ESQUIRE
ROBIN LOCKE NAGELE, ESQUIRE
Post & Schell, P.C.
1800 J.F.K. Boulevard
19th Floor
Philadelphia, PA 19103
Counsel for Mercy Haverford Hospital
d/b/a Mercy Community Hospital

9/17/02 DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS

DATE

Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

# ON BEHALF OF MERCY HAVERFORD HOSPITAL D/B/A MERCY COMMUNITY HOSPITAL

GAVIN KERR, PRESIDENT

Siphler 16, 2002

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Counsel for Mercy Haverford Hospital d/b/a Mercy Community Hospital

9/17/02 DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

DATE

7/26/02